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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,088	07/18/2003	Robert P. Bennett	IVGN 332	1853
65482 7590 05/15/2007 INVITROGEN CORPORATION C/O INTELLEVATE P.O. BOX 52050 MINNEAPOLIS, MN 55402			EXAMINER HORNING, MICHELLE S	
			ART UNIT 1648	PAPER NUMBER
			MAIL DATE 05/15/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/622,088

Applicant(s)

BENNETT ET AL.

Examiner

Michelle Horning

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/27/2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17,19,20,22,24-27 and 44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17,19,20,22,24-27 and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 7/18/2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 5/21/04

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This office action is responsive to communication filed 3/27/2007. The status of the claims is as follows: claims 1-16, 18, 21, 23 and 28-43 have been canceled and claims 17, 19-20, 22, 24-27 and 44 are under current examination.

Withdrawn Claim Rejections

The following rejections filed 9/6/2006 have been withdrawn due to claim amendments and a misinterpretation of the art by the examiner.

1. 35 USC 112, 2nd paragraph; and
2. 35 USC 102.

IDS

The one hundred and eighty-six paged IDS filed 5/21/2004, consisting of nearly 674 references, has been considered for the nine claims under examination. There are references that did not have the required dates and these were not considered.

Drawings

The drawings are objected to because many of them show nothing, for example Figures 25, 29, 30 and 38. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being

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amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

New Claim Objections

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See paragraph 195 of the instant application.

New Claim Rejections

35 U.S.C. 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17, 19-20, 22 and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al (1982). The limitations of the rejected claims are as follows: 1. a method of constructing a recombinant virus comprising the following steps: a. providing a 1st nucleic acid molecule comprising all or a portion of one or more viral genomes and at least a first and second recombination site that do not recombine with each other; b. contacting the first nucleic acid molecule with a 2nd nucleic acid molecule comprising a sequence of interest flanked by at least a third and fourth recombination site under conditions such that recombination occurs between first and third and second and fourth recombination sites; and c. introducing the nucleic acid of the above step into a cell for packaging; 2. wherein the first nucleic acid comprises all or a portion of a retroviral genome, more specifically, a lentiviral genome; 3. wherein the first nucleic acid comprises all or a portion of at least one RNA virus genome; 4. wherein the first nucleic

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acid is a plasmid with an origin of replication and selectable marker; 5. wherein the portion of the second nucleic acid between the recombinant sites comprises a nucleotide sequence of interest, more specifically, a sequence encoding a polypeptide; and 6. wherein digestion of the first nucleic acid with a restriction enzyme cleaves the nucleic acid at a site between the recombination sites.

Anderson et al meets most of the limitations above. This reference describes a method in which a reaction occurs between a gene of interest and a simian virus 40 plasmid via recombination (whole document, see Abstract). The gene of interest is the herpes simplex virus-1 gene encoding for thymidine kinase, also the selectable marker (see Abstract and Introduction). Table 2 demonstrates many of the different restriction enzymes used and may also be considered selectable markers to the ordinary artisan (see SV40 carrier). Of note, the simian virus is an example of a retrovirus, a lentivirus and an RNA virus. Anderson et al does not expressly state that there is a replication origin in the SV40 DNA; however, given that this reference describes its transformation of *E. coli* and the multiple copies were generated, the SV40 DNA must possess a replication origin (see Plasmid Rescue, page 2748).

Anderson et al does not teach introducing the nucleic acid into a cell for packaging *following* recombination; transforming of DNA, however, is taught by this reference. This would have been obvious to one of ordinary skill in the art to do. One would have been motivated to do so in order to generate multiple DNA copies for further experimentation, including restriction enzyme assays. One would have had a reasonable expectation of success given that such a skill is so well known, commonly

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employed and the method is taught by the Anderson et reference (see Materials and Methods). Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 17 and 44 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 17 and 18 of U.S.

Patent No. 7198924. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to the recombination of two nucleic acid molecules via attL/attR recombination.

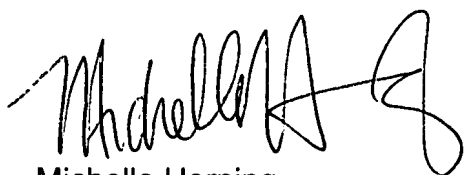
CONCLUSION

No claim is allowed.

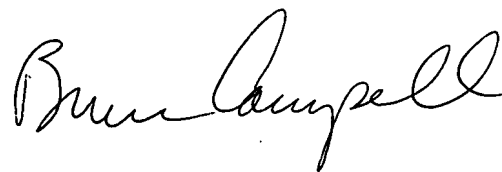
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Horning whose telephone number is 571-272-9036. The examiner can normally be reached on Monday-Friday, 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 570-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for unpublished application is available through Private PAIR only. For more information about PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michelle Horning
Patent Examiner



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